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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,024

02/09/2005

Katsumi Ihara

2005-0097A

3975

513 7590 07/09/2010
WENDEROTH, LIND & PONACK, L.L.P.
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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

07/09/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com
coa@wenderoth.com

Notice of Allowability	Application No.	Applicant(s)	
	10/524,024	IHARA ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to paper filed 04 June 2010.
2. ☒ The allowed claim(s) is/are 1-8.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>6/4/2010</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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DETAILED ACTION

Status of the Application

Receipt of the Information Disclosure Statement (IDS) filed 06/04/10 is acknowledged.

Claims 1-8 are pending in this action. Claim 1 has been amended. New claims 7 and 8 have been added. Claims 1-8 are allowed.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 06/04/10 was filed after the mailing date of the Non-Final Office Action on 09/02/09. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

* * * * *

Allowable Subject Matter

Claims 1-8 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art of record (Kim *et al.* - WO 01/87276; Brantl *et al.* - US 4,826,686; McQuinn US 5,113,860; Yamaguchi *et al.* - US 5,820,877 and Miller, III *et al.* - US 2004/0086551) does not disclose nor fairly suggest or teach a fentanyl patch as instantly claimed wherein the drug layer 'consists essentially of' and/or 'consists of' fentanyl (or its salt), methyl vinyl ether-maleic anhydride copolymer as the adhesive agent and a thickener selected from one of hydroxypropyl cellulose, hydroxypropylmethyl cellulose and hydroxyethyl cellulose.

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Applicant, in their response filed 01/29/10, has limited the drug layer of the instant patch to the components described above, based on the “consisting essentially of” and/or “consisting of” language now employed. This language excludes the required additional elements and/or features disclosed in the preparations of the art. Consequently, the instant invention is rendered non-obvious and patentable over the cited art of record.

The instant invention demonstrates an improvement over the formulations of the art in that, for example, it does not need any complex procedures when it is applied; is comfortable in the oral cavity; can quickly increase the serum concentration as the drug is absorbed; makes less transfer of the drug into the gastrointestinal tract by preventing the drug release into other parts of the oral cavity except the applied region; is easily removable; is usable as a rescue preparation for pangs during therapy for cancer pain and is highly safe.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

July 6, 2010